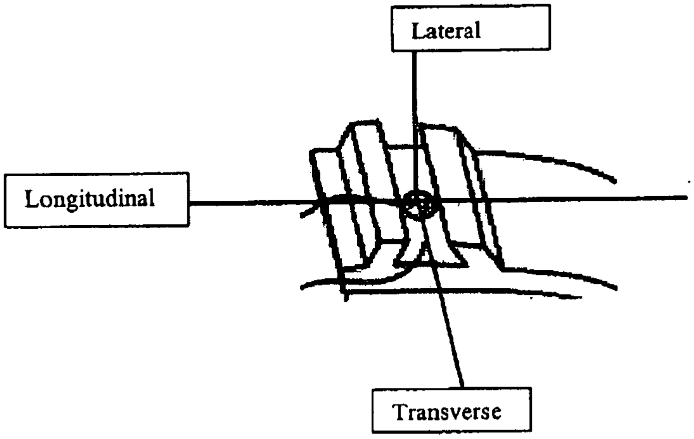
REMARKS

In the December 15, 2004, Office Action, the Examiner indicated that claim 13 was not present. By this Amendment, Applicants have added the missing claim, as claim 13 in order to maintain consecutive numbering. If the newly added claim should instead be designated claim 19, Applicants request the Examiner to do so by Examiner's Amendment, or alternatively to advise Applicants that a supplemental Amendment is needed.

In the Office Action, the Examiner rejected claims 1, 2, 10-12, 14-17 under 35 USC §102(b) as being anticipated by Antebi USP 4,592,355; rejected claims 1-4, 12 and 14-18 under 35 USC §102(b) as being anticipated by Gleichaut et al USP 4,532,868; and objected to claims 6-9, indicating that they would be allowable if rewritten into independent form. Applicants submit that all claims as originally submitted arc novel and non-obvious over the cited art and respectfully request withdrawal of the rejections.

In the Office Action, the Examiner asserts that both Antebi and Gleichaut disclose implantable bands having transverse attachment mechanisms. However, neither of these references discloses transverse attachment mechanisms. The application describes three directions in relation to the band: longitudinal, lateral and transverse. These directions are illustrated below in relation to a portion of figure 3:



As indicated at paragraph 33 of the application, the longitudinal strap extends in the longitudinal direction, even when the band is implanted and has an arcuate configuration.

In the August 25, 2005, Office Action the Examiner recites definitions of "transverse" from Merriam-Webster OnLine, and asserts that "[t]he claims do not specify in what direction the attachment mechanism transverses (sic) the device". The Examiner then used "transverse" as being any direction "acting, lying, or being across" the longitudinal axis of the band. In making his rejection, the Examiner referred to the width and the thickness of the Antebi strap 11 as both being transverse. Under the Examiner's interpretation, "transverse" means any direction which intersects, but is not collinear with the longitudinal axis of the band: Not just the infinite number of directions lying in the plane perpendicular to the longitudinal axis, but the infinite number of direction lying in any plane which does not contain the longitudinal axis.

However, the assertion that "[t]he claims do not specify in what direction the attachment mechanism transverses (sic) the device" and that both the width and thickness of the Antebi strap are transverse indicates that the Examiner has ignored the clear and consistent use of the directions in the specification and the explicit diagram set forth above and in the previous Response. The Examiner "cannot look at the ordinary meaning of the term ... in a vacuum. Rather [he] must look at the ordinary meaning in the context of the written description and the prosecution history." Medrad, Inc. v. MRI Devices Corp., 401 F.3d 1313 (Fed. Cir. 2005). The Examiner's interpretation is inconsistent with the clear and consistent use of these relative directions in the specification, and contrary to how a person of ordinary skill in the art would the claim term within the context of the claim, the entire patent and the prosecution history.

It also appears from the Office Action that the Examiner considers every three dimensional object as being longitudinal, lateral and transverse. specific failed to consider is a transverse opening because it has a dimension in the transverse direction. By this logic, the opening is a longitudinal opening and a lateral opening, rendering the terms longitudinal, lateral and transverse meaningless.

The Examiner's assertion that the opening through the head 13 transverses (sic) the strap because it extends the thickness of the strap is untenable. A person of ordinary skill in the art, upon reading the specification, would clearly understand that the opening in the head 13 is a lateral opening within the meaning of the patent application. The same applies to the Examiner's assertion that the teeth 12 are transverse teeth because "the teeth 12 transverse (sic) the width of the strap". However, the teeth extend laterally outwardly, as well as having a longitudinal width. Applying the Examiner's interpretation of the dimensional directions of the present application, the teeth are longitudinal teeth, lateral teeth and transverse teeth. However, to a person of ordinary skill in the art of tooth design would understand, the teeth extend laterally since that it the direction of the tooth profile: The face width of the teeth 12 extend transversely, but a person of ordinary skill in the art of tooth design would not refer to the teeth as transverse teeth. It is further noted that the tooth thickness of teeth 12 extends in the longitudinal direction, not the thickness of the strap.

It appears that the Examiner considers every three dimensional object as being longitudinal, lateral and transverse. However, the Examiner's interpretation must follow the meaning which a person of ordinary skill would give the claim term within the context of the claim, the entire patent and the prosecution history. When this is done, and the Antebi reference is interpreted properly, the Examiner's assertions based on Antebi cannot stand.

However, regardless of the Examiner's misapplication of the orthogonal directions, Antebi completely lacks any disclosure or suggestion of a transverse attachment mechanism. As is clear from the patent application, a transverse attachment mechanism requires relative transverse movement between the first and second end portions of the implantable band. Antebi discloses only longitudinal movement of a first end relative to a second in combination with lateral movement of the second end relative to the first end. Neither perspective of relative movement (whether from the first end or the second end) includes any transverse movement which is required for engagement or disengagement.

In regard to claim 16, Antebi discloses a one way strap for forming a loop which can only be made smaller. The pawl 15 of Antebi is configured to prevent decoupling and as such is not configured to decouple with application of force. Thus, neither end of the Antebi strap is configured to be decoupled by applying a decoupling force perpendicular to the separating force. Antebi clearly lacks any teaching or suggestion of cinched down as far as the length and the strap and location of the teeth permit. Although the strap reaches a point at which it cannot advance further through the opening, it is not due to the opening, but only to the physical limitations of the length of the strap.

Schockaert

In the August 25, 2005, Office Action, the Examiner asserts that Schockaert discloses an "implantable band" "for treatment of a medical condition" which is "configured to encircle an anatomical passageway". At least that assertion is inherent in rejecting claims 1-5, and 12-18 under 35 USC §102(b).

Schockaert discloses a belt which is worn around the waist. It is not configured "to encircle an anatomical passageway". A person of ordinary skill in this art would not consider a belt to be encircling an anatomical passageway. Nor is the Schockaert belt capable of encircling an anatomical passageway.

A person of ordinary skill in the art also knows and understands that an implantable band for treatment of a medical condition requires that the band be constructed of a bio-compatible material. However, Schockaert discloses that elements 4 and 5, and the plate 6 can be any material. Schockaert also discloses that the belt may be of "any material". Although Schockaert indicates that the parts could be plastic, "any material" is not a recitation of bio-compatible material, nor does it teach or suggest bio-compatible material. There is simply no need for Schockaert to be concerned with material suitable for implantation: Schockaert is a belt worn outside of a body, not inside.

In regard to the bump and detent of claims 10 and 11, the Examiner asserts that Schockaert discloses recesses 17 and 18 which are shaped complementarily to bumps 12 and 16. However, this rejection reveals a lack of attention to the specific disclosure of Schockaert. The lead line for numeral 12 leads to the rounded end of dovetail pin 7, a which is not a bump. Applicants suspect that the Examiner intended to refer to the leg 15 which extends from dovetail pin 7 corresponding to the leg 16 extending from dovetail pin 8. However, even with this correction, the rejection inaccurately describes Schockaert. Legs 15 and 16 are located at the lower end of dovetail pins 7 and 8, spaced a decoupling force. The separating force in Antebi is longitudinal (when considered relative to the end 14) or lateral (when considered relative the head 13). Decoupling the two ends of the Antebi strap, aside from requiring destruction of either the teeth 12 or the pawl 15, is in not perpendicular to the separating force: It is exactly the same direction.

Furthermore, relative movement between the ends of the Antebi strap can occur even though the ends are not decoupled. The loop formed Antebi strap is made smaller by such relative movement while the ends are coupled.

In repeating his previous assertion that "the transverse attachment mechanism comprise (sic) a circuitous path defined by the first end portion, and a lateral member carried by the second end portion, the path having a width which correspond (sic) to dimensions of the lateral member to allow the lateral (sic) to be mover (sic) along the path; the path is configured to require coordinated transverse and circumferential relative movement between the first and second portions to move the lateral member along the path", the Examiner appears to have merely rotely reiterated portions of the previous Office Action that can only have been founded on an interpretation that the transverse direction defined by the specification of the present patent application is instead the lateral direction defined by the specification of the present patent application. The Examiner has not, in the Antebi figures incorporated into the Office Action, explained how this quoted passage can be found in the Antebi strap. It is clear that Antebi has only circumferential movement (when considered relative to the end 14) or lateral movement (when considered relative the head 13). Despite these two perspectives which permit the movement to be described either as circumferential (longitudinal) or lateral, there is only one movement direction: There is no path that is configured to require coordinated movement in two directions. The strap end 14 is simply inserted into the opening and pulled longitudinally. The movement of the pawl 15 within the head 13 is not relative movement between the two end portions. It is also clear that Antebi lacks a circuitous path.

Applicants further point out that the lateral opening found in Antebi does not terminate in circumferentially spaced positions. The path of the strap through the head of the Antebi strap has no termination. This is why the strap, as all cable ties, can be apart and remote from cavities 17 and 18. Cavities 17 and 18, which are spherical, are not shaped complementarily to legs 15 and 16, and cannot engage them. The Examiner's attention is drawn to Figure 3, which illustrates protuberance 29 which is disposed to engage cavity 18.

Apparently in regard to claims 12-15, the Examiner asserts "the transverse attachment mechanism comprise (sic) a circuitous path defined by the first end portion, and a lateral member carried by the second end portion, the path having a width which correspond (sic) to dimensions of the lateral member to allow the lateral (sic) to be move (sic) along the path; the path is configured to require coordinated transverse and circumferential relative movement between the first and second portions to move the lateral member along the path".

However Applicants are at a loss as to how this mostly verbatim recitation of the corresponding portion of the Antebi rejection is relevant to the claims. The Examiner has indicated that elements 3 and 4 of Schockaert comprise the first end portion while element 5 comprises the second end portion. While the Examiner may be interpreting one of these as a circuitous path, it has absolutely no relevance to the terms of the claims. Under the Examiner's assertion, as applied to claim 12, elements 3 and 4 define a circuitous path. Apparently the examiner considers the belt looped about post 33 of the element 4 as following a circuitous path. However, element 3 is connected to element 4 through the dovetail, and element 4 is connected to the second end element 5 (under the Examiner's analysis) through another dovetail. But, claim 12 recites a circuitous path defined by the first end portion which allows the lateral member carried by the second end portion to be moved along the path. Although is it unclear what structure of element 5 of Schockaert that the Examiner considers to be a lateral member, no part of element 5 (the second end portion) can be moved along the path followed by the belt through element 4.

Even reversing the definition of first and second end portions so that the first end, which defines the circuitous path, is considered to be element 5, and the second end, which carries a lateral member, is considered to be elements 3 and 4, the Examiner's rejection cannot stand. Again, although is it unclear what structure of elements 3 and 4 of

Schockaert that the Examiner considers to be a lateral member, no part of elements 3 and 4 (the second end portion) can be moved along the path followed by the belt through element 5. The dovetail pin, 8, cannot follow the path of the belt around post 33.

Further, the belt being looped around the post 33 is not a transverse attachment mechanism. Transverse movement between the belt and the element 5 does not occur to connect the two together.

Thus, Schockaert does not anticipate any of the claims. It does not disclose an implantable band; it does not disclose a strap configured to encircle an anatomical passageway; it does not disclose a circuitous path.

Schockaert does disclose a double dovetail connection. But, there is nothing in Schockaert which suggests modifying implantable bands with a dovetail connection. Schockaert is non-analogous art. As stated by the Federal Circuit in the two leading cases on analogous art rejections: "In order to rely on a reference as a basis for rejection..., the reference must either be in the field of applicant's endeavor, or if not, then be reasonably pertinent to the particular problem with which the inventor was concerned." *In re Oetiker,* 977 F.2d 1443,1446 (Fed, Cir. 1992). "A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor's endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem." *In re Clay,* 966 F.2d 656, 659 (Fed. Cir. 1992).

Thus, the purposes of both the invention and the prior art are important in determining whether the reference is reasonably pertinent to the problem the invention attempts to solve. *Id.* If a reference's disclosure has the same purpose as the claimed invention, the reference relates to the same problem, and that fact supports use of that reference in an obviousness rejection. *Id.* If an invention is directed to a different purpose, the inventor would have had less motivation to consider it. *Id.*

It is clear that the present application is in a different field of endeavor and is not reasonably pertinent to the particular problem with which the Applicants were concerned. The present invention is an implantable band for treatment of a medical condition, which includes a strap configured to encircle an anatomical passageway. In sharp contrast,